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STPDTS

DEPT PLEASE PASS TO USTR JCHOE-GROVES STATE FOR EEB/TPP/IPE JBOGER USDOC FOR ITA/MAC/EUR/MROGERS

E.O. 12958: N/A

TAGS: KIPR ETRD ECON LO

SUBJECT: IPR: SLOVAKIA PROVIDES STORAGE FACILITY FOR DRUG

DATA

REF: A. SECSTATE 45109

\_B. BRATISLAVA 66

- 11. Summary: The Slovak Ministry of Health (MOH) has resolved a long-running USG concern related to the protection of intellectual property by providing a new, secure facility for the storage of confidential drug company data. End Summary.
- 12. As a part of the 2006 Special 301 review process the MOH committed to procuring a new storage facility for proprietary drug application data. Prior to 2006 the data had been stored in a facility that lacked adequate security and was adjacent to facilities owned by a generic drug manufacturer. MOH's commitment to resolve this long-standing issue, together with legislative amendments to provide for a linkage between the Industrial Property Office and the Drug Control Authority (SUKL), led to Slovakia's removal from the Special 301 Watch List in 2006. Slovakia has remained off the list since 2006 (Reftel A.)
- 13. MOH had originally planned to complete the new facility by 2007, but the project was repeatedly delayed due to problems with the building that MOH had designated for this purpose, and was not expected to be ready before summer 2009. As an interim measure SUKL, which is responsible for the protection of drug company data, provided temporary security upgrades at the current facility.
- 14. During a May 2008 courtesy call with Ambassador, Health Minister Valentovic informed that MOH had located and leased a brand new facility in Rovinka, on the outskirts of Bratislava, and would begin transferring the drug company files in the next couple of weeks. EmbOffs visited the site on May 30 and were fully satisfied that the new, modern 1000 square meter storage facility is fully under the control of SUKL and addresses all of our previous security concerns. SUKL has already started moving some of the files, a process that it hopes to complete by the end of this month.

OBSITNIK